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Bionomics (BNO)

BNC210 Licensed; Bionomics on its way to Self-Sustainability

Recommendation
Buy (unchanged)
Price
0.58
Target (12 months)
1.50 (unchanged)
Risk
Speculative

Expected Return

Capital growth	159%
Dividend yield	0
Total expected return	159%

Company Data & Ratios

Enterprise value	\$181.0M
Market cap	\$200.0M
Issued capital	344.8M
Free float	100%
Avg. daily vol. (52wk)	0.78
12 month price range	\$0.315-\$0.77

GICS sector

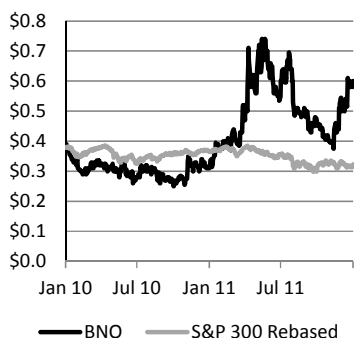
Healthcare Equipment and Services

Disclosure: Bell Potter Securities acted as Bell Potter Securities acted as lead manager for a A\$48.5 capital raising and sell-down in May 2011 and received fees for that service.

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.52	0.48	0.31
Absolute (%)	16.50	26.32	93.55
Rel market (%)	17.52	21.88	106.48

Absolute Price



SOURCE: IRESS

Bionomics' CNS drug BNC210 out licensed to Ironwood

Bionomics (BNO) announced today the licensing of its CNS drug BNC210 and related compounds to US based Ironwood Pharmaceuticals (IRWD) for US\$3mn as an upfront payment plus another US\$10mn over the next 2 years in research funding and milestones. The deal also involves a further US\$332mn payable on clinical and regulatory milestones being achieved, making it a potential US\$345mn deal. Additionally BNO will receive undisclosed royalties on net sales of BNC210. **IRWD will bear all further development and commercialization costs of BNC210 for exclusive worldwide rights to BNC210 and other CNS assets.** We expect IRWD to take BNC210 to Phase II clinical trials in the next 2 years, which would translate to a commercial launch by 2018/2019 vs. our earlier expected 2016/2017 timeframe.

Our take on what the deal means for BNO

The deal is a plus for BNO and further cements its position as a drug discovery company focused on innovation and helping patients with high unmet needs. **Ironwood, though a \$1.2bn market cap company, is a good partner for BNO to have because** 1) Ironwood has strength and expertise in the symptomatic disorders space and is currently on the verge of launching a blockbuster drug Linaclotide, for gastrointestinal disorders (GI), 2) It is well funded and has collaborations with several large global pharma/biotech companies validating its stellar market reputation and also opening up a future M&A possibility 3) IRWD's pipeline is early stage and BNC210 complements Linaclotide in terms of target market and specialist sales force since anxiety disorders are a co-morbidity of GI disorders. This makes BNC210 the next most important product for them.

The deal is the largest seen for a Phase I asset in the Australian market. The upfront payment is smaller than we expected, however, the total deal size and our belief that the undisclosed royalties would be in the 14-17% range leave us extremely excited for Bionomics future revenue streams from the product. It is important to note that BNC210 is targeted at a US\$12bn global market for anxiety drugs. We see today's deal putting Bionomics on the path to self-funding for its ~\$7m annual burn rate while awaiting further payments in the form of milestones and royalties to negate the possibility of capital raisings in the near future. The deal would allow BNO to prioritize the development of BNC105 and other development programs.

Valuation and Price Target

We re-iterate our Spec Buy Recommendation on BNO. We value Bionomics on a probability-weighted DCF basis at \$1.41 base case and \$2.51 optimistic case. Our target price of \$1.50 sits at the low-point of our DCF range. Our valuation and price target remain unchanged for now given that the larger than expected deal size is offset by the pushing back of the launch timeline for BNC210 and the smaller upfront payment. We view BNO's announcement today as a start of a series of significant news flow over the next twelve months assisting in the stock being re-rated to our target price of \$1.50.

Bionomics Licenses BNC210 to Ironwood Pharmaceuticals

Terms of the BNO – Ironwood Deal

Under the agreement:

- Ironwood will pay Bionomics US\$3mn as upfront payment payable initially followed by another US\$10mn in research funding and milestone payments payable over the next 2 years.
- Bionomics is to receive US\$332mn additionally as clinical and regulatory milestones.
- Ironwood will receive exclusive rights to commercialize BNC210 and other related compounds while assuming responsibility for funding and conducting Phase II & III trials and subsequent commercialization of BNC210.
- Bionomics will also receive undisclosed royalties on net sales of BNC210.

Our take on what the deal means for BNO

On the face of it today's deal announcement is a milestone event for Bionomics given that it has been successful in partnering BNC210 at an early stage with a partner whose expertise in the space of symptomatic disorders can be leveraged to fully unlock BNC210's potential. This is a sentiment positive for the company and in our view has given it more visibility globally especially in the US among investors and Big Pharma/Biotech companies. The deal along with Bionomics' existing collaboration with Merck Serono provides validation for Bionomics as a drug discovery company, increases our confidence on the credibility of the BNO management and we believe would increase market confidence in the company, paving way for future partnerships. On the financial side, the total deal size is one of the largest in the Australian market in terms of a Phase I asset, however we are cognizant of the small upfront payment falling short of market expectations and understand that lack of details on the royalty stream is likely to temper the enthusiasm of the market on the news. However, we choose to take a long-term view on Bionomics' future revenue streams from the deal and argue that:

- Though the upfront payment is smaller than expected the deal size is huge for a Phase I asset. BNO has the potential to get substantial milestone payments which given the early stage clinical success of BNC210 in terms of efficacy and better safety profile than existing drugs, considering its blockbuster potential, considering the due diligence likely to have been done by Ironwood, increases the probability of Bionomics achieving the clinical targets and triggering those payments.
- We believe that the undisclosed royalties could be in the 14-17% range of net sales looking at average rates in historical transactions, which we think is reasonable to assume in view of our high regard for Bionomics' advisory team and therefore Bionomics' bargaining power. BNC210 is targeted at a US\$12bn global market for anxiety drugs and a 14-17% royalty stream leave us extremely excited for BNO's future revenue streams from the product.
- Today's deal which injects \$3mn immediate cash into the company and in all likelihood another \$10mn over the next 24 months, puts BNO on the path to self-sustainability for its ~\$7m annual burn rate while awaiting further payments in the form of milestones and additional undisclosed royalties. We believe BNO will not need to raise funds in the near future.

- The deal allows BNO to focus its efforts and resources on developing its anti-cancer drug BNC105 which is a much larger market opportunity for BNO and also enable it to advance its other pipeline candidates and developmental programmes.
- The partnering deal with Ironwood has de-risked the BNC210 programme from a regulatory perspective. Ironwood management commented on the conference call today that they would engage with the FDA on the future development path of BNC210, especially relating to trial endpoints based on Patient Reported Outcomes (PROs). We expect Ironwood's experience in dealing with the FDA on PROs for its flagship product Linaclotide will be valuable and help the company to position BNC210 similarly with the FDA. This in turn makes the new 2018/2019 timeline for commercial launch of the product more achievable and overall success more likely.
- Ironwood Pharmaceuticals (IRWD) is a good partner for Bionomics to have as we detail below.

Who is Ironwood?

Ironwood is a development stage specialty pharmaceutical company focused on developing innovative treatments, targeting therapeutic areas with high unmet need. It is focused primarily on symptomatic disorders such as GI disorders. The company is incorporated in Delaware and headquartered in Massachusetts. Ironwood was initially incorporated as Microbia in 1998 and in 2008 it changed its name to Ironwood pharmaceuticals. Ironwood's strategy till date has been to invest substantially in early stage research; contrary to traditional specialty pharma companies which predominantly in-license/acquire late-stage products to build their pipeline.

Linaclotide, the company's lead product is a potential blockbuster. With Linaclotide IRWD is targeting a market which is highly underserved (very few marketed competitor products in the space) and characterized with a high unmet need. Linaclotide is a first-in-class, late-phase gastrointestinal product which is awaiting approval from the FDA for use in chronic constipation (CC) and constipation-predominant irritable bowel syndrome (IBS-C) and from the EMA for IBS-C. The PDUFA date for Linaclotide's review by FDA is likely to be June 2012, with commercial launch expected in 4Q 2012. *If approved by EMA Linaclotide will be the first approved product for IBS-C in Europe.* Based on the vigorous research programme (four pivotal phase 3 trials) and strong efficacy and safety data, the probability of Linaclotide obtaining regulatory approval are extremely high. Ironwood has partnered with Forest Laboratories in the U.S. to co-develop and co-commercialize Linaclotide, and has also partnered the compound internationally with Almirall in the EU territories and with Astellas in Japan, Thailand, South Korea, Taiwan, Indonesia and Philippines. Ironwood has retained Linaclotide rights in India, Singapore, China and key Latin American markets. Ironwood intends to pursue other GI indications for Linaclotide and also extend its usage to the pediatric population once the CC & IBS-C indications are approved.

In addition to Linaclotide, Ironwood has undisclosed preclinical and early stage candidates in gastrointestinal disorders, pain and inflammation and respiratory diseases. Ironwood is also undertaking preclinical research in the cardiovascular disease space.

Management continues to actively evaluate business development opportunities. As evidenced by today's deal announcement and the Depomed research collaboration agreement earlier this year, the management actively evaluates external licensing and collaboration opportunities to augment its in-house pipeline development efforts. Ironwood raised \$203mn from an IPO in February 2010 by issuing class A shares. **Ironwood had ~\$175mn in cash and cash equivalents at the end of 3Q 2011 and management**

guided their end of FY 11 target for cash and cash equivalents to be more than \$150mn. Additionally, Ironwood is to receive up to \$85 mn milestone payment in 2H 2012 from Forest Laboratories on FDA approval of Linaclotide and up to \$100mn in sales milestones and equal share of Linaclotide's profit/loss following commercial launch of the product. Clinical and regulatory milestones are also receivable from Ex-US partners Almirall and Astellas over the next couple of years. Management has also stated that Ironwood should not need to raise cash until 2014. We believe the combined funds offset by Ironwood's share of Linaclotide's US commercialization costs and other working capital requirements should be sufficient for Ironwood to fund today's deal with Bionomics.

Ironwood has safeguards against hostile takeovers. Ironwood's corporate structure is made up of two classes of stocks- Class A and Class B, each class of stock having a different voting structure. The structure allows Class B share holders (who are basically pre-IPO investors in the company) to have a 10-1 voting right vs. Class A shareholders in situations likely to result in change of control. One of the prominent Class B shareholders is Venrock, the venture capital arm of the Rockefeller family. Furthermore as part of the Linaclotide agreement Forest Laboratories and Almirall invested in Ironwood's stock and IRWD has standstill agreements in place against hostile takeovers with all 3 of its Linaclotide partners.

Why the deal with Bionomics makes sense for Ironwood

Ironwood is a development stage company with a market capitalization of US\$1.2 bn. In spite of having a blockbuster potential late stage candidate, Ironwood has certain vulnerabilities which can impact its future growth and today's licensing of BNC210 from Bionomics is likely to reduce those vulnerabilities. Advantages for Ironwood are:

Reduce the dependency on Linaclotide

- Linaclotide its lead product is a potential blockbuster; however, it is the only late stage product which Ironwood has in its portfolio. All other candidates in Ironwood's pipeline are either preclinical or early stage and undisclosed which makes it difficult to establish their potential. Linaclotide is likely to be the only source of revenue for the company for some time, and given the various partnership arrangements in place for Linaclotide, the revenue stream from it for Ironwood is limited.
- Also Linaclotide for IBS-C and CC has patent exclusivity going out to 2025 in US, 2024 in EU and the Japan patent which is pending if granted will also go out to 2024. Even assuming some patent extension with use in pediatric population (6 months) or use in other indications, the patent exclusivity can be extended to 2027/2028. Ironwood needed a candidate to fill the revenue gap arising from Linaclotide's patent expiry, which would have a similar if not better revenue stream than Linaclotide.
- Linaclotide is expected to launch in the US in 4Q 2012 and in the EU in 2H 2013. In its 3Q 2011 investor presentation management indicated that they expect Linaclotide's launch trajectory to emerge over 1-2 years picking up meaningfully only in 2015, citing the launch trajectories of successful products like Prilosec and Zelnorm as examples and an analysis of revenue streams of all primary care launches since 2005 as the reason behind their conservative guidance.

Thus for Ironwood augmenting its pipeline with a Phase II ready candidate BNC210, which again is a potential blockbuster given the early safety and efficacy data from two Phase Ib/IIa trials establishing its superiority over existing anxiety drugs is a really good bet.

BNC210 complements flagship product Linaclotide

From a strategic point of view, one of the main advantages to Ironwood from licensing BNC210 is the synergies obtained from treating patients on Linaclotide with anxiety drug BNC210. Anxiety disorder is a co-morbidity of many GI disorders and a lot of IBS patients

suffer from anxiety disorder as well and we see the BNC210 deal to be synergistic with Linaclotide in terms of the target market. Also since the target market is the same, the same specialist sales force can be utilized to market BNC210.

Make it more attractive as a takeover candidate

We believe that Ironwood would be more attractive to large-cap pharmaceutical companies as a likely acquisition candidate, having now two products with blockbuster potential which target markets which are highly underserved and characterized by high unmet need. For Ironwood the biggest challenge it may face in the future is being unable to build its pipeline beyond Linaclotide. In that eventuality the management will realistically have to consider selling the assets of the company. We believe BNC210 makes Ironwood more attractive to a potential acquirer. **We note here that one of Ironwood's partners Forest Laboratories is extremely interested in the anxiety/depression space as evidenced from its acquisition of 'Clinical Data Inc.' in April 2011 primarily for their anxiety drug Viibryd for US\$1.2bn.** Forest Labs recently lost patent exclusivity on its blockbuster drug Lexapro in September 2011, which follows that they are '**shopping**' to fill the revenue gap. BNC210 does make acquiring Ironwood for Forest Labs more attractive in our view.

Seven reasons to like Bionomics

Bionomics has transformed itself from a genomics company into a drug discovery company

Introducing Bionomics, ASX Code BNO. Bionomics is an Adelaide-based drug discovery company with two products in early-stage clinical trials – BNC210, an anti-anxiety drug, and BNC105, a cancer drug whose ability as a Vascular Disrupting Agent makes it highly suitable for the treatment of a variety of solid tumours. Both drugs have performed well in both pre-clinical and clinical work. The first-in-class BNC210 is an effective and ‘clean’ anxiety drug. The clinical data on BNC210 indicates that the compound can relieve anxiety quickly, without causing sedation or being addictive, two common side effects of current anti-anxiety medications. Given its attractiveness in terms of the large market for currently prescribed branded anxiety drugs, BNC210 was licensed early and we also see potential for an early licensing deal for BNC105. Bionomics also has a pipeline of pre-clinical compounds, as well as valuable drug discovery technology. Bionomics started its listed life in 1999 as a genomics company but in the mid-2000s transformed itself into a drug discovery company. The 2005 acquisition of Iliad Chemicals brought considerable drug discovery capability, the BNC105 programme, and a pipeline of pre-clinical opportunities.

1. **Bionomics’ BNC210 partnering deal with Ironwood has de-risked the company.** Bionomics’ partnering deal with Ironwood Pharma will inject \$3mn in upfront payments and another \$10mn over the next two years as research funding & milestone payments allowing Bionomics to be on the way to self-sustainability for its ~\$7m annual burn rate while awaiting further US\$332mn payments in the form of milestones and additional undisclosed royalties.
2. **Bionomics’ BNC105 compound is an effective Vascular Disrupting Agent.** The pre-clinical and clinical data to date has shown that BNC105 is highly effective at dismantling the vasculature of tumours while leaving healthy blood vessels untouched. It also seems to be highly effective in treating all solid tumours. This ability points to a strong payoff in the cancer space given the large global sales for Roche’s Avastin drug.
3. **Bionomics has valuable drug discovery technology.** Bionomics’ proprietary Multicore, Angene and ionX drug and target discovery platforms have provided the company with an engine for future growth which we believe potential acquirers of the company will value highly. These platforms have helped create a valuable pipeline beyond BNC210 and BNC105, including as-yet unpartnered programmes in Alzheimer’s disease and epilepsy.
4. **There is potential for Bionomics to license BNC105.** We think the fact that Bionomics has already partnered its Multiple Sclerosis programme to Merck Serono and BNC210 to Ironwood Pharmaceuticals points to the chance for further deals. We think that a licensing deal for BNC105 would further de-risk the company and provide sufficient funds to invest in rest of the pipeline.
5. **Bionomics has good management.** We like the commercial approach that CEO Dr Deborah Rathjen has developed. Deborah and her colleagues have transformed Bionomics since 2005 and taken it further up the value curve.
6. **Bionomics is undervalued, on our numbers.** We value Bionomics on a probability-weighted DCF basis at \$1.41 base case and \$2.51 optimistic case. Our \$1.50 price target sits at the low point of this range. We anticipate Bionomics being re-rated by the market on the basis of progress in the BNC105 renal cancer trial, as well as other significant news flow over the next twelve months assisting in the stock being re-rated to our target price.

7. **Solid news flow expected in 2012.** We expect that pre-clinical and clinical data and, potentially, licensing deals could provide some good news flow over the next twelve months including a) Progress into part II of BNC105's Phase II trial in metastatic renal cell carcinoma; b) Initiation of the ovarian cancer trial, with interim data in 2012; c) Progress on the development of BNC210; d) Potential selection of a lead molecule in the Merck Serono collaboration in MS; e) Preclinical progress on the $\alpha 7$ nAChR programme and f) Potential licensing announcement.

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Accumulate: Expect total return between 5% and 15% on a 12 month view. For stocks regarded as 'Speculative' a return of between 5% and 30% is expected.

Hold: Expect total return between -5% and 5% on a 12 month view

Reduce: Expect total return between -15% and -5% on a 12 month view

Sell: Expect <-15% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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